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Our Case No. 10546/6

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: John W. Wong et al.))
U.S. Patent Application Serial No.: 09/424,431) Examiner: Mendoza, Michael G.) Group Art Unit No. 3731
Filed: March 16, 2000))
For: METHOD AND APPARATUS FOR DELIVERING RADIATION THERAPY DURING SUSPENDED VENTILATION))))

REPLY BRIEF

Mail Stop Appeal Brief-Patents Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

This Reply is in response to the Examiner's Answer mailed November 30, 2005.

I. ARGUMENT

A. Nonanalogous Art

Appellants' Appeal Brief filed on September 8, 2005 (hereinafter "Appellants' Appeal Brief") asserted that Anderson et al. was directed to nonanalogous art. In particular, Appellants showed that Anderson et al. was not within the Appellants' field of endeavor by pointing to Appellants' own teachings in the "Field of the Invention" section of Appellants' Specification and the preamble of claim 15 (Appellants' Appeal Brief, P. 8, II. 11-26). In the Final Office Action of March 8, 2005 (hereinafter "the Final Office Action") it was asserted that Appellants' claimed invention was in the more general field of delivering radiation therapy. The Examiner's Answer has repeated this assertion with the statement "[t]he device of Anderson also supply [sic] a treatment/therapy to a user in the form of radiation" (Examiner's Answer, P. 3, II. 17-18). However, the Examiner's Answer does not stop there. It now asserts, for the first time, that Appellants' claimed invention is within an even more general field – devices that are "used in the medical art" (Examiner's Answer, P. 3, II. 16-17).

Both of the above characterizations of the Appellants' field of endeavor are erroneous. In the case *In re Clay*, 966 F.2d 656, 23 USPQ2d 1058 (Fed. Cir.

1992), the Applicant had claims directed to a process for obtaining access to a dead volume of a storage tank containing a refined liquid hydrocarbon by preparing a gelation solution that filled the dead volume resulting in access to the refined liquid hydrocarbon that was present in the dead volume. The United States Patent Office rejected the claims as being rendered obvious, in part, by a patent to Sydansk that disclosed a similar gel that reduced the permeability of hydrocarbon-bearing formations. Id. at 658, 23 USPQ2d at 1060. Applicant traversed the rejection because Sydansk was directed to nonanalogous art. Id., 23 USPQ2d at 1060. The United States Patent Office found that Sydansk and the rejected claims were within Applicant's field of endeavor - 'maximizing withdrawal of petroleum stored in petroleum reserves.' Id. at 659, 23 USPQ2d at 1060. The Court of Appeals for the Federal Circuit held to the contrary pointing out that Sydansk could not be considered within the Applicant's field of endeavor merely because they both relate to the petroleum industry. Id., 23 USPQ2d at 1060. Instead, the Court compared the environments in which the Applicant's invention and Sydansk were performed and found them so disparate that they could not be considered to regard the same field of endeavor. Id., 23 USPQ2d at 1060. Applying a similar analysis to the present situation, it is apparent that Anderson et al. is not within Appellants' field of endeavor. The inventions of

independent claims 15 and 33 and their dependent claims regard suspending ventilation and delivering radiation therapy during such suspension of ventilation. Movement of internal organs, such as the lungs, during the radiation therapy envisioned by claims 15 and 33 could lead to the undesired movement of an area to be treated, such as a tumor, and lead to irradiating healthy tissue (Appellants' Specification, P. 3, II. 4-18). In contrast, Anderson et al. is not concerned with the movement of internal organs or tumors, since it applies its doses of UV radiation to the exterior skin of a patient in an effort to treat skin disorders (Anderson et al., Col. 5, II. 61-67). Since the environments in which radiation is applied regarding the claimed inventions and Anderson et al. are so different, Anderson et al. is not directed to the same field of endeavor as the claims. See, In re Clay.

B. No Motivation to Combine

1. Dietz/Rienmueller

Appellants' Appeal Brief has asserted that the combination of Dietz, Rienmueller et al. and Anderson et al. under 35 U.S.C. § 103 is improper, because of a lack of motivation to do so. The Examiner's Answer asserts for the first time that "[t]he combination of Dietz/Rienmuller teaches interrupting examination" (Examiner's Answer, P. 3, II. 21-22). This assertion has no basis in

fact. Indeed, the Final Office Action at page 4, lines 1-2, conceded "that Dietz/Rienmueller fails to teach an abort switch adapted to halt the apparatus." Furthermore, the Examiner's Answer fails to point to one passage in the references that disclose such interrupting.

A review of Dietz does not disclose interrupting examination. Instead, Dietz discloses a breath exposure synchronizer that senses flow during breathing by a patient in order to synchronize exposure of an x-ray film to avoid blurring of radiographs (Col. 5, II. 23-26). The synchronizer is used to signal when an x-ray film should be exposed during the breathing process (Col. 1, I. 62 – Col. 2, I. 37).

Rienmueller et al. also does not disclose interrupting examination.

Rienmueller et al. discloses sensing the flow of air from a patient via a spirometer (Col. 3, II. 1-13). A trigger signal is sent to a computer 5 when a prescribed rate of flow is reached (Col. 3, II. 14-27). While the respiratory flow can be mechanically interrupted upon reaching the prescribed rate of flow, there is no suggestion that the examination itself is interrupted (Col. 3, II. 28-46). Indeed, during the interruption of respiratory flow, therapy or imaging is performed on the patient (Col. 3, II. 44-46).

2. "Adapted to" Language

Independent claim 15 recites "an abort switch adapted to halt the apparatus for administering radiation therapy and open a closed one of the first and second selectively operable valves" (emphasis added). Furthermore, independent claim 33 recites "an abort switch adapted to halt the apparatus for administering radiation therapy and open the selectively operable valve" (emphasis added). The Examiner's Answer asserts for the first time that it has been held that the above "adapted" to clauses are "not a positive limitation and do "not constitute a limitation in any patentable sense" (Examiner's Answer, P. 4, II. 2-5). No case law has been cited to support this assertion. This is understandable since the assertion is contrary to case law and U.S. Patent Office policy. In particular, Section 2173.05(g) of the Manual of Patent Examining Procedure explicitly states that:

There is nothing inherently wrong with defining some part of an invention in functional terms. Functional language does not, in and of itself, render a claim improper. *In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA 1971).

The courts have also accepted language similar to that recited in claims 15 and 33. For example, in the unpublished case *R.A.C.C. Indus. Inc. v. Stun-Tech Inc.*, 49 USPQ2d 1793 (Fed. Cir. 1998), *cert. denied*, 526 U.S. 1098 (1999), the Court

of Appeals for the Federal Circuit interpreted the phrase "said mounting means being adapted for concealment." The Court held that the functional language "adapted for concealment" was a positive recitation that limited "the scope of these claims to devices that have the *capability* of being concealed" (emphasis as in original). *Id.* at 1797.

Applying the *R.A.C.C.* case to claim 15 of the present Appeal, the phrase "an abort switch adapted to halt the apparatus for administering radiation therapy and open a closed one of the first and second selectively operable valves" should be interpreted to be a positive limitation. In particular, the phrase should be interpreted so that the recited abort switch has a structure so that it is capable of halting the apparatus for administrating radiation therapy and is capable of opening a closed one of two selectively operable valves. Similarly, claim 33's phrase "an abort switch adapted to halt the apparatus for administering radiation therapy and open the selectively operable valve" should be interpreted so that the recited abort switch has a structure so that it is capable of halting the apparatus for administrating radiation therapy and is capable of opening a selectively operable valve. It is noted that throughout prosecution the Examiner has treated the phrases as positive recitations up until the filing of the Examiner's Answer.

3. Official Notice

The Examiner's Answer appears to be giving Official Notice that "it is well known in the art of medical equipment to include a kill-switch or an "on/off" function in case there is a malfunction or parameters are not met" (Examiner's Answer, P. 4, II. 5-7). This assertion has never been made before during prosecution of the application. Official Notice as to certain facts should only be taken when the facts "are capable of instant and unquestionable demonstration as being well known." MPEP § 2144.03A. That is not the case here.

Furthermore, it is improper that there has been no presentation of evidence in the record that supports the Official Notice assertion recited above. MPEP § 2144.03B. For the above reasons, the reliance on Official Notice that it is well known to use a kill switch or an "on/off" function in the art of medical equipment is improper.

C. Status of Rejection of Claims 29 and 31

The Examiner's Answer has clarified that claims 29 and 31 were finally rejected in the Final Office Action under 35 U.S.C. §103(a) as being obvious in view of Dietz, Rienmueller et al. and Anderson et al. alone and U.S. Patents Nos. 5,111,809; 5,479,920 and 6,571,796 are not relied on to reject the claims (Examiner's Answer, P. 4, II. 5-7). If that is the case, then their mention in the

Final Office Action should be ignored since they are <u>not</u> being used to reject the claims. To consider them in the context of Appellants' arguments would only confuse the issues at hand.

In addition, Appellants traverse the Examiner's Answers' statement that the references show that it is well known in the art to use one-way valves to the extent that it implies that U.S. Patent No. 6, 571,796 qualifies as prior art which it does not. Furthermore, the statement is traversed to the extent that it may be construed to mean that the remaining two patents suggest using the recited abort switch in either Dietz, Rienmueller et al. or Anderson et al., which they do not.

For the reasons given previously in Appellants' Appeal Brief and the present Reply, Appellants respectfully submit that the rejections should be withdrawn and the claims should be allowed.

Respectfully_submitted,

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